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EXAMINER	
TONGUE, LAKIA J	
ART UNIT	**PAPER NUMBER**
1645	

SHORTENED STATUTORY PERIOD OF RESPONSE	NOTIFICATION DATE	DELIVERY MODE
3 MONTHS	03/12/2007	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Notice of this Office communication was sent electronically on the above-indicated "Notification Date" and has a shortened statutory period for reply of 3 MONTHS from 03/12/2007.

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Office Action Summary	Application No.	Applicant(s)	
	10/735,481	GARBE ET AL.	
	Examiner	Art Unit	
	Lakia J. Tongue	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 February 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *6,31,35,37,41,43 and 47-51* is/are pending in the application.

4a) Of the above claim(s) *6,31,35,41 and 47* is/are withdrawn from consideration.

5)☒ Claim(s) *49-51* is/are allowed.

6)☒ Claim(s) *37,43 and 48* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's response filed on February 6, 2007 is acknowledged. Claims 6, 31, 35, 37, 41, 43, and 47-51 are pending and under consideration. Claims 6, 31, 37, 43, and 48 have been amended. Claims 6, 31, 35, 41, and 47 have been withdrawn. Claims 2 and 33 have been canceled. Claims 37, 43, and 48-51 are under examination.

Rejections Withdrawn

1. In view of Applicants' amendment, the rejection of claims 2, 37, 43, and 48 under 35 U.S.C. 102(b) as being anticipated by Akerblom et al. (U.S. Patent 5,834,192) is withdrawn. The cancellation of claim 2 has rendered the rejection of that claim moot.

2. The rejection of claim 2 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description/new matter requirement is withdrawn. Cancellation of claim 2 has rendered the rejection of that claim moot.

3. The rejection of claim 2 under 35 U.S.C. 112, second paragraph as being rendered vague and indefinite by the use of the phrase "substantially in isolation" is withdrawn. Cancellation of claim 2 has rendered the rejection of that claim moot.

4. The rejection of claim 48 under 35 U.S.C. 112, second paragraph as being rendered vague and indefinite by the use of the phrase "consisting essentially of a fragment of the C-terminal....said fragment comprising a maximum of 50 amino acids of said C-terminal" is withdrawn in light of the amendment thereto.

Rejections Maintained

5. The rejection claim 48 and currently amended claims 37 and 43 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement because the claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention is maintained for the reasons set forth in the Previous office action in the rejection of claim 48.

Applicant argues that:

1) Claim 48 has been amended to now recite an isolated antimicrobially active peptide consisting of a fragment of the C-terminal of dermicidin protein of SEQ ID NO: 1, said fragment comprising a maximum of 50 contiguous amino acids of said C-terminal.

2) A skilled artisan would have no difficulty figuring out which end of a 110-amino acid protein is its C-terminal, or how to make the claimed peptides and test them for antimicrobial activity, based on the teachings in the specification as filed and the state of the art at the time the invention was made.

Applicant's arguments have been fully considered and deemed non-persuasive.

The instant invention is drawn to an isolated antimicrobially active peptide consisting of a fragment of the C-terminal of dermcidin protein of SEQ ID NO: 1, said fragment comprising a maximum of 50 contiguous amino acids of said C-terminal.

With regard to Points 1 and 2, the claims are broadly drawn to an isolated antimicrobially active peptide comprising a maximum of 50 contiguous amino acids of said C-terminal. Applicant still hasn't identified which structure (i.e. which amino acids of said C-terminal) must be present in order to maintain the claimed function of the peptide. It is not clear what specifically constitutes the C-terminal or where the C-terminal begins and ends internally. The specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession of the claimed invention. Contrary to Applicant's assertions the specification does not provide a written description of the invention of claim 48. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention.

Lastly, The Guidelines further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot

be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. As evidenced by Bowie et al (Science, 1990, 257:1306-1310), the effects of sequence dissimilarities upon protein structure and function cannot be predicted. Bowie et al. teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function, carry out the instructions of the genome. Bowie et al. further teach that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. (column 1, page 1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (column 2, page 1306). Therefore, absent a detailed and particular description of a representative number, or at least a substantial number of the fragments of the genus of dermcidin proteins, the skilled artisan could not immediately recognize or distinguish members of the claimed genus having antimicrobial activity. Therefore, because the art is unpredictable, in accordance with the Guidelines, the description of an isolated antimicrobially active peptide consisiting of a fragment of the

C-terminal of dermcidin protein of SEQ ID NO: 1, said fragment comprising a maximum of 50 contiguous amino acids of said C-terminal is not deemed representative of the genus of immunogenic compositions to which the claims refer and hence do not meet the written description requirements.

As previously presented, to fulfill the written description requirements set forth under 35 USC § 112, first paragraph, the specification must describe at least a substantial number of the members of the claimed genus, or alternatively describe a representative member of the claimed genus, which shares a particularly defining feature common to at least a substantial number of the members of the claimed genus, which would enable the skilled artisan to immediately recognize and distinguish its members from others, so as to reasonably convey to the skilled artisan that Applicant has possession the claimed invention.

Moreover, the skilled artisan cannot envision the detailed chemical structure of the encompassed proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. The polypeptide itself is required. See Fiers v. Revel, 25 USPQ2d 1601, 1606 (CAFC 1993) and Amgen Inc. V. Chugai Pharmaceutical Co. Ltd., 18 USPQ2d 1016. In Fiddes v. Baird, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

Finally, University of California v. Eli Lilly and Co., 43 USPQ2d 1398, 1404. 1405 held that: ...To fulfill the written description requirement, a patent specification must describe an invention and does so in sufficient detail that one skilled in the art can clearly conclude that "the inventor invented the claimed invention." Lockwood v. American Airlines Inc. , 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); In re Gosteli , 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." Lockwood, 107 F.3d at 1572, 41 USPQ2datl966.

An adequate written description of the claimed dermcidin derivative, "requires a precise definition, such as by structure, formula, chemical name, or physical properties," not a mere wish or plan for obtaining the claimed chemical invention. Fiers v. Revel, 984 F.2d 1164, 1171, 25 USPQ2d 1601, 1606 (Fed. Cir. 1993).

However, the specification is silent as to what amino acids must be present in order for a given fragment to possess the recited functional characteristics (antimicrobial activity). Is the maximum of 50 amino acids contiguous, possess substitutions or deletions? The specification does not provide a written description of the invention of claim 48. The purpose of the "written description" requirement is broader than to merely explain how to "make and use"; the applicant must convey with reasonable clarity to

those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the "written description" inquiry, whatever is now claimed.

The Guidelines further state, "[f]or inventions in an unpredictable art, adequate written description of a genus which embraces widely variant species cannot be achieved by disclosing only one species within the genus" (Id. at 1106); accordingly, it follows that an adequate written description of a genus cannot be achieved in the absence of a disclosure of at least one species within the genus. As evidenced by Bowie et al (Science, 1990, 257:1306-1310), the effects of sequence dissimilarities upon protein structure and function cannot be predicted. Bowie et al. teach that an amino acid sequence encodes a message that determines the shape and function of a protein and that it is the ability of these proteins to fold into unique three-dimensional structures that allows them to function, carry out the instructions of the genome. Bowie et al. further teach that the problem of predicting protein structure from sequence data and in turn utilizing predicted structural determinations to ascertain functional aspects of the protein is extremely complex. (column 1, page 1306). Bowie et al further teach that while it is known that many amino acid substitutions are possible in any given protein, the position within the protein's sequence where such amino acid substitutions can be made with a reasonable expectation of maintaining function are limited. Certain positions in the sequence are critical to the three dimensional structure/function relationship and these regions can tolerate only conservative substitutions or no substitutions (column 2, page 1306). Therefore, absent a detailed and particular

description of a representative number, or at least a substantial number of the fragments of the genus of dermcidin proteins, the skilled artisan could not immediately recognize or distinguish members of the claimed genus having antimicrobial activity. Therefore, because the art is unpredictable, in accordance with the Guidelines, the description of a fragment of the C-terminal of dermcidin protein is not deemed representative of the genus of immunogenic compositions to which the claims refer and hence do not meet the written description requirements.

New Grounds of Rejection Necessitated by Amendment

Claim Objections

6. Claims 37 and 43 are objected to because of the following informalities: both claims depend on a higher numbered claim (i.e. claim 37 and 43 depend on claim 48). Appropriate correction is required.

35 USC § 112, New Matter Rejection

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

7. Claim 48 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one

skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This is a new matter rejection.

Applicant has amended claim 48 to recite in part "comprising a maximum of 50 contiguous amino acids of said C-terminal". This phrase does not appear in the specification, or original claims as filed. Applicant does not point out specific basis for this limitation in the application, and none is apparent.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 48 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 48 is rendered vague and indefinite by the use of the term "contiguous". It is unclear what is meant by said term, as it is not explicitly defined in the specification. What constitutes "contiguous"? What core features/structures must be maintained? As written, it is impossible to determine the metes and bounds of the claimed invention.

Claim 48 is rendered vague and indefinite by the use of the phrase "an isolated antimicrobially active peptide consisting of a fragment of the C-terminal of dermcidin protein of SEQ ID NO: 1, said fragment comprising". It is unclear what is meant by said phrase, as it is not explicitly defined in the specification. How does the antimicrobially active peptide consist of a fragment of the C-terminal of dermcidin protein of SEQ ID

NO: 1, and comprise a maximum of 50 contiguous amino acids of said C-terminal? As written, it is impossible to determine the metes and bounds of the claimed invention.

Conclusion

9. Claims 49-51 are allowed.

10. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakia J. Tongue whose telephone number is 571-272-2921. The examiner can normally be reached on Monday-Friday 8-5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jeffery Siew can be reached on 571-272-0787. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only.

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LJT
2/22/07

ROBERT A. ZEMAN
PRIMARY EXAMINER